K081049

510(k) Summary

CryoCath Technologies Inc.

FlexCath® Steerable Sheath and Dilator

JUN 27 2008

1. SPONSOR

CryoCath Technologies Inc.
16771 Chemin Ste-Marie
Kirkland, Quebec
H9H 5H3, CANADA

Official Correspondant:	Jean-Pierre Desmarais
	Chief Scientific Officer
Telephone:	514-694-1212 ext 226
Fax:	514-694-7075
Date Prepared:	April 09, 2008

2. DEVICE NAME

Device Trade Name:	FlexCath® Steerable Sheath & Dilator
Common/Usual Name:	FlexCath® Steerable Sheath & Dilator
Classification Name:	Steerable Catheter, 21CFR 870.1280
Device Classification:	Class II

3. PREDICATE DEVICE

FlexCath® Steerable Sheath & Dilator (K070357)

4. DEVICE DESCRIPTION

The FlexCath® Steerable Sheath is a deflectable catheter introducer used to facilitate placing a catheter through the skin into the artery or vein.

It is comprised of the following two (2) main sections: the shaft and the handle. A dilator is also part of the package.

5. INTENDED USE

The FlexCath® Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The Sheath deflection facilitates catheter positioning.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Technological characteristics such as product design and materials of the FlexCath® Steerable Sheath are substantially equivalent to the predicate devices. Where dimensional and material differences exist between the proposed device and the predicate devices, bench testing and biocompatibility testing demonstrated that these differences do not adversely affect safety and effectiveness.

7. PERFORMANCE TESTING

Information submitted in this Special 510k for the FlexCath® Steerable Sheath and Dilator is substantially equivalent to the predicate devices listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

CryoCath Technologies Inc.
c/o Fred Milder
Applied Physics
52 West Basin Ridge
Galisteo, NM 87540

Re: K081049
Trade Name: FlexCath® Steerable Sheath & Dilator
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: June 5, 2008
Received: June 6, 2008

Dear Mr. Milder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-240-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081049

Device Name: FlexCath® Steerable Sheath & Dilator

Indications For Use:

The FlexCath® Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The Sheath deflection facilitates catheter positioning.

Contraindications:

The FlexCath® Steerable Sheath is contraindicated for placement in the left atrium or ventricle if:

- The patient has an intra-atrial septal patch or has had other surgical intervention in or adjacent to the intra-atrial septum.
- The patient has had a previous embolic event from the left side of the heart within 2 months of the procedure.
- The patient has known or suspected atrial myxoma.

FlexCath® Steerable Sheath should not be used to perform the transseptal puncture.

Prescription Use __X__ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081049